MINUTES OF THE NUTRITION COORDINATING COMMITTEE (NCC) MEETING, NATIONAL INSTITUTES OF HEALTH (NIH)
Building 45 (Natcher), Conference Room A
December 5, 2013 2:00 – 4:00 PM

WELCOME

Dr. Van Hubbard, Director of the NIH Division of Nutrition Research Coordination (DNRC), convened the meeting at 2:06 PM and welcomed participants. Phone participants included the following: Dr. Rachel Ballard-Barbash, NIH NCI; Dr. Rosalind Breslow, NIH NIAAA; Dr. Paul Cotton, NIH NINR; Ms. Mary Cutting, NIH NIDCR; Dr. Sheila Dreher-Lesnick, FDA CBER; Dr. Mary Evans, NIH NIDDK; Dr. Roberto Flores, NIH NCI; Dr. Stephanie Goodwin, HHS ODPHP; Dr. Judy Hannah, NIH NIA; Ms. Joanne Karimbakas, NIH NIDDK; Dr. Young Kim, NIH NCI; Dr. Richard Kotz, FDA CDRH; Dr. Jessica Leighton, FDA; Dr. Kathleen Michaels, NIH FIC; Dr. John Milner, USDA ARS; Dr. Jen Patro, FDA CFSAN; Dr. Katrina Piercy, HHS ODPHP; Dr. Carol Pontzer, NIH NCCAM; Dr. Tonse Raju, NIH NICHD; Dr. Sharon Ross, NIH NCI; Dr. Gloria Solano-Aguilar, USDA ARS; Dr. Barbara Sorkin, NIH ODS; Dr. Paula Trumbo, FDA CFSAN; and Dr. Lois Tully, NIH NINR: The agenda for the meeting is provided as Appendix A and the list of attendees is provided as Appendix B.

APPROVAL OF MINUTES FROM THE SEPTEMBER 5, 2013 NCC MEETING

Minutes from the September 5, 2013 NCC meeting had previously been sent to NCC members via email. Dr. Hubbard asked if there were any other corrections to the minutes. There were none. Dr. Dan Raiten, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), made a motion to approve the minutes, and Dr. Shirley Blakely, the Food and Drug Administration, seconded the motion. The minutes were thus approved and will be posted on the DNRC website, http://www.dnrc.nih.gov, along with the minutes from the previous NCC meetings.

NUTRITION R&D OPPORTUNITIES TO IMPROVE GLOBAL HEALTH

Dr. Hillary Chen, a Policy Analyst with the White House, serves as the Assistant Director of the White House Office of Science and Technology Policy (OSTP), Technology and Innovation Division. Dr. Chen has played a pivotal role in coordinating and overseeing the administration's global health initiatives. Prior to working at OSTP, she worked for the Global Initiative as a member of the Global Health Team, and she also spent a year in India working on health and education programs for the Deshpande Foundation. Dr. Chen's presentation focused on the OSTP roles which include providing science and technology advice to the President, ensuring that Executive Branch policies are science-based, and coordinating partnership and research activities that promote the global health

agenda. She described several nutrition research and development activities and she outlined opportunities that have potential to improve global health.

OSTP uses several tools to advance and communicate the administration's global health agenda, including statements of national policy such as Executive Orders and Presidential Policy Directives, the President's budget, Congressional legislation, the President's events and speeches, and meetings with bilateral and multilateral scientific leadership and numerous partners to discuss matters of common interest. Nutrition research and development (R&D) opportunities include efforts to reduce the global disease burden; initiatives such as Feed the Future (http://www.feedthefuture.gov/) and the Global Health Initiative (http://www.ghi.gov/); improving undernutrition and reducing non-communicable disease (NCD) burden; supporting food systems research and providing humanitarian relief; improving food availability, healthy behaviors and the sustainability of the global food supply.

The OSTP is focusing on three areas in particular: 1) improving the business platform for nutrition research by leveraging private sector R&D opportunities; 2) promoting scientific research in emerging areas such as the microbiome and sustainable food production practices; and 3) identifying nutrition policy needs and strategies to implement them effectively. In terms of the business platform for nutrition research, she cited public-private partnership opportunities such as the Global Alliance for Improved Nutrition (GAIN http://www.gainhealth.org/about-gain).

The GAIN alliance was created in 2002 at a Special Session of the UN General Assembly on Children. The Swiss Foundation GAIN supports public-private partnerships to increase access to improve health and nutritional status. Today, more than 600 companies are part of the GAIN effort. Private companies are engaged in collaborative efforts with NIH, universities, and others to develop improved biomarkers of health, modern food delivery channels, new product formulations and packaging systems, and effective strategies to change nutrition behavior. The GAIN Secretariat plans to hire a Research Manager in the near future to oversee several efforts.

The emerging scientific research areas GAIN and its partners are focused on have tremendous potential to improve global health, with microbiome products and microbiome complements to therapeutic products for humans and animals being one of them. The microbiome research and policy agenda topics include methods to manipulate the microbiome and regulatory frameworks for food products. Additionally, sustainable food product development in a world experiencing changing climate patterns is a critical area to meet the global demand for food. The applications of modern food science must be adapted to a global development context, and this too will require research funding.

Dr. Chen briefly described nutrition strategies and opportunities for the NIH nutrition research community to engage with OSTP and other partners. From her vantage, NIH input would be very helpful to develop a comprehensive nutrition research agenda and build efforts that are currently underway. She mentioned that the *USAID Nutrition* report is expected this winter. Additionally, there are two potential U.S. Government-sponsored interagency nutrition strategies that are relevant to the NIH nutrition research mission: Nutrition for Global Health and the Nutrition R&D Strategy. Input is needed on the U.S. Government activities to identify the "clear value" propositions—positioning research programs such that they are valuable to partners including the NIH, companies, and others. NIH input would be beneficial to identify new collaborations and expand existing public-private partnerships. "Big ideas" are of interest to the OSTP, the NIH, and many other groups. Bold, paradigm-shifting nutrition research has great potential to improve global health and inform nutrition and health policies.

In her closing remarks, Dr. Chen briefly mentioned several other OSTP activities related to biosecurity, antimicrobial resistance, platform technologies, and behavioral insights. One of Dr. Chen's colleagues is leading the behavior research team and she offered to provide contact information to interested NIH staff.

During the group discussion, Dr. Hubbard mentioned that the Interagency Committee on Human Nutrition Research (ICHNR) will discuss the formation of a new subcommittee on global nutrition. Dr. Isabel Walls, USDA, added that Dr. Cathie Woteki, the Under Secretary for Research, Education & Economics, supports the development of a comprehensive, US Government-wide national strategic plan for nutrition research under the aegis of the ICHNR. This topic will be a key agenda item at the next ICHNR meeting, which will take place in February. Dr. Chen has been invited to participate in this effort. The national plan should provide input into the USAID global strategic plan previously mentioned by Dr. Chen. When asked about funding commitments to support efforts to develop the business platform for the nutrition initiatives, Dr. Chen mentioned that there is no formal funding yet for the nutrition initiatives. As was mentioned earlier however, the GAIN Secretariat will fund the research manager position and companies are funding research activities. Additional funding is needed to support Feed the Future and the Global Health Initiative.

Dr. Raiten commented on his efforts to engage with USAID as he serves as an international representative and has been active in USAID's Scale Up Nutrition (SUN http://scalingupnutrition.org/) initiative, a global movement launched in 2012 that engages governments, the United Nations, businesses, researchers, and others to improve nutrition using a comprehensive framework to address the factors that impact nutritional status.

GUIDANCE FOR CLINICAL INVESTIGATORS, SPONSORS AND IRBs FOR IND

Paula Trumbo, FDA/CFSAN spoke about guidance FDA issued in September to assist clinical investigators, sponsors, sponsor-investigators, and institutional review boards (IRBs) in determining whether research studies involving human subjects must be conducted under an investigational new drug application (IND), as described in title 21 of the Code of Federal Regulations, part 312 (21 CFR part 312) (the IND regulations). Link to the Guidance: http://www.regulations.gov/#!documentDetail;D=FDA-2010-D-0503-0016 Although FDA guidance is non-binding, it has potential impact on the type of nutrition research investigators will undertake. Dr. Trumbo provided a brief overview and illustrative examples of the FDA guidance. Her opening remarks discussed relevant FDA regulations.

With respect to dietary supplements, under the Dietary Supplement Health and Education Act of 1994 (DSHEA), a dietary supplement is defined, in part, as a product taken by mouth that is intended to supplement the diet and that contains one or more dietary ingredients. Dietary ingredients include vitamins, minerals, herbs and other botanicals, amino acids, other dietary substances intended to supplement the diet, and concentrates, metabolites, constituents, extracts, or combinations of the preceding types of ingredients. Under DSHEA, a dietary supplement is not considered a drug and is not subject to the premarket approval requirements for drugs if the intended use for which it is marketed is only to affect the structure or any function of the body (i.e., not intended to be used for a therapeutic purpose). The need for IND when conducting clinical investigations to evaluate a dietary supplement is determined by the intent of the clinical investigation. If the clinical investigation is intended only to evaluate the dietary supplement's effect (includes nutrient and non-nutrient supplements) on the structure or function of the body, an IND is not required.

With respect to conventional foods, Section 201(f) of the FD&C Act (21 U.S.C. 321(f)) defines a food as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." For studies intended to evaluate the effects of a food, the analysis for whether an IND is needed turns on the intent of the clinical investigation. As is the case for a dietary supplement, a food is considered to be a drug if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," except that a food may bear an authorized health claim about reducing the risk of a disease without becoming a drug (see section VI.D.3. Therefore, a clinical investigation that is intended to evaluate the effect of a food on a disease would require an IND under part 312.

Dr. Trumbo cited several examples during her presentation. For example, a clinical investigation intended to evaluate the effect of vitamin D on a site-specific cancer or the effect of vitamin D on a surrogate endpoint such as serum LDL cholesterol as part of a disease process would require INDs. No INDs are required if the research is examining nutrient bioavailability, metabolism, or balance. Structure-function endpoints that are not disease-related are also exempt. Examples of research conducted with infant formulas were also discussed. Research conducted to examine growth outcomes does not require an IND, whereas research that examines outcomes such as immune response would require an IND.

During the group discussion, Dr. Hubbard requested that NIH staff whose grants portfolios might be affected contact their grantees to determine if issues related to the FDA guidance have arisen. He commented that the burden of the IND application step has been magnified in some cases. Obtaining an IND is not always a major undertaking—even for food research projects. Additionally, if an investigator does not receive disapproval within thirty (30) days of the IND application, the research can proceed as planned.

ELSI PROBIOTICS FRAMEWORK

Dr. Linda Duffy, NCCAM, provided a summary of recent activities related to the NIH Probiotic and Prebiotic Working Group and the Human Microbiome Project (HMP).

Of particular interest is the Ethical, Legal and Social Issues (ELSI) study (funded by the NIH Human Microbiome Project), which seeks "to examine whether the current U.S. regulatory framework for probiotics: (i) adequately addresses issues of safety and effectiveness; (ii) provides sufficient information to consumers to make informed choices; and (iii) sufficiently allows for, or at least does not discourage, research on potential therapeutic benefits." In 2010, researchers at the University of Maryland Baltimore were awarded a grant from the NIH HMP to examine and make recommendations regarding the regulation of probiotics. The grant funded several meetings with a selected group of stakeholders and experts. Dr. Duffy shared the white paper, *Federal regulation of probiotics: An analysis of the existing regulatory framework and recommendations for alternative frameworks,* which summarizes the discussions and recommendations that emerged from the stakeholder meetings. She also shared an article published in the Science Magazine entitled: *"Probiotics: Finding the Right Regulatory Balance",* which published sections of the ELSI white paper.

The ELSI study builds on the 2011 AHRQ report, the "Safety of Probiotics to Reduce Risk and Prevent or Treat Disease." The white paper is not intended to give solutions but defines some of the key challenges and potential areas for reform. One of the key concerns raised by stakeholders is the desire to conduct research on probiotics in a manner that is safe and appropriate but not subject to the research restrictions of drugs, as

they may not be applicable to certain commonly used products. Whether an investigational new drug application (IND) is required and what potential impact this would have on future studies was discussed and reported in the white paper.

Dr. Duffy emphasized that more can be done through interagency collaborations and that by working together we can begin to integrate data and address some of the identified research gaps.

Resources:

1. Guidance for Clinical Investigators, Sponsors, and IRBs - Investigational New Drug Applications (INDs) — Determining Whether Human Research Studies Can Be Conducted Without an IND

2. Federal Regulation of Probiotics: An Analysis of the Existing Regulatory Framework and Recommendations for Alternative Frameworks

3. Probiotics: Finding the Right Regulatory Balance

OFFICE OF DIETARY SUPPLEMENTS (ODS) UPDATE

Dr. Becky Costello, ODS, provided the following updates:

ODS Monthly Seminar Series

The next seminar of the 2013/14 series will take place on December 11, 2013.

Elizabeth Johnson, Ph.D.
Scientist, Jean Mayer USDA Human Nutrition Research Center on Aging
Friedman School of Nutrition Science and Policy, Tufts University

Topic: "Lutein, From the Eye to the Brain"

Location: *6100 Executive Blvd, 1st floor conference room*

ODS Fact Sheets

ODS maintains a series of fact sheets that give an overview of individual vitamins, minerals and other dietary supplements. ODS has fact sheets in two versions—Health Professional and QuickFacts. ODS recently posted a selenium *QuickFacts for Consumers* and an updated *Magnesium Fact Sheet for Health Professionals*. The link to all of the ODS Fact Sheets is: http://ods.od.nih.gov/factsheets/list-all/

3rd International Vitamin Conference – Save the Date

The 3rd International Vitamin Conference will take place in Washington DC on May 12-15, 2014. Registration is not open yet but will be available soon at: http://www.vitaminconference.com/

OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION (ODPHP) UPDATE

Dr. Katrina Piercy provided the following update:

The second Dietary Guidelines for Americans Advisory Committee meeting will be held January 13-14th at the new NIH Building 35 (Neuroscience Research Center) Conference Facility) in Bethesda, MD. The meeting is open to the public and registration will be open in the next few days on www.dietaryguidelines.gov to attend the meeting in-person or via webcast. Monday's half day meeting will include 3 expert speakers, Michael McGinnis from the IOM, Kate Clancy, a Food Systems Consultant, and Sue Krebs-Smith, from the National Cancer Institute. The full day meeting on Tuesday will include oral testimony from the public and updates from each of the five subcommittees.

Also, a reminder that the public comment database is available on www.dietaryguidelines.gov. All comments are shared with the committee and you can also view other comments that have been submitted.

REPORTS FROM NCC MEMBERS AND LIAISONS

Ms. Kathryn McMurry provided several announcements from NHLBI.

1) **Four guidelines** focused on the management of overweight and obesity weight in adults, lifestyle modifications to reduce cardiovascular risk, management of blood cholesterol, and assessment of cardiovascular risk were released on November 12th by the American College of Cardiology (ACC) and the American Heart Association (AHA), in collaboration with the National Heart, Lung, and Blood Institute (NHLBI) and key professional societies. A fifth guideline addressing hypertension will be published in JAMA. These guidelines are based on rigorous, comprehensive, systematic evidence reviews sponsored by the National Heart, Lung, and Blood Institute. The evidence reports will be posted on the NHLBI website in the near future.

   The Lifestyle CVD Final Recommendations Table can be found in **Appendix C.**

2) On November 8th, the NIH and the Children's Museum of Manhattan (CMOM) announced the release of EatPlayGrow™, a new educational curriculum designed to keep children healthy through creative strategies developed specifically for families with young children (ages 2 to 5). The curriculum was adapted from the *We Can!*® obesity prevention program (originally for ages 8-13). CMOM has also

created the *EatSleepPlay™: Building Health Every Day* exhibit with over 70 interactive stations that allow families to experience ways to create a healthier lifestyle together.

3) Ms. Karen Donato has announced that she will be retiring from the NIH on January 3rd. Ms. Donato is the Acting Director of the Division for the Application of Research Discoveries at NHLBI and is also the Coordinator for Overweight and Obesity Research Applications. She has been a tremendous asset to NIH over the past 30 years and has played a pivotal role in the development of education programs, clinical guidelines, and curricula for clinicians, patients and the public. Ms. Donato was recently recognized by the Obesity Society with the Atkinson-Stern Award for her significant work to improve the lives of those affected by obesity through public policy. She will be greatly missed.

Dr. Dan Raiten, NICHD provided two announcements:

1) The B-24 Report on the evaluation of the evidence base to support the inclusion of infants and children from birth to 24 months of age in the *Dietary Guidelines for Americans* should be published in AJCN in February.

2) The Micronutrient Forum Global Conference will take place June 2-6, 2014. Abstracts are being accepted until December 6th. For more information, visit: http://www.micronutrientforum.org/

CURRENT DNRC UPDATE OF ACTIVITIES

Nutrition Education Subcommittee (NES):

The NES reviews nutrition education materials for consistency with the *Dietary Guidelines for Americans (DGAs), 2010.*

NES Chair, Dr. Margaret McDowell, NIH/DNRC reported that the NES completed five dietary guidance reviews since the September NCC meeting and is currently reviewing two USDA submissions.

Completed NES Reviews:

1. **FDA, Center for Food Safety and Applied Nutrition (CFSAN) *Interactive Food Labels***: The Interactive Label tool was developed to help consumers and health educators understand the contents of the Nutrition Facts Label. The tool was designed to have an engaging and interactive format. Consumers and health educators will be able to browse the Nutrition Facts Label content (e.g. calories, serving size, and

nutrients), scroll over components of the label to find short descriptions, and access in-depth fact sheets and detailed information on the label components and/or nutrients. The Interactive Label will reside on a web page on the www.FDA.gov/ food Internet site. The link to the FDA Nutrition Facts Label Programs and Materials is: http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm20026097.htm

2. **NIH National Cancer Institute (NCI) *Vitamin D and Cancer Fact Sheet*:** NCI updated the Fact Sheet. An expedited dietary guidance review was completed by HHS and USDA reviewers. The fact sheet is available online. The link is: http://www.cancer.gov/cancertopics/factsheet/prevention/vitamin-D

3. **NIH National Center for Complementary and Alternative Medicine (NCCAM) *Diabetes and Dietary Supplements Fact Sheet***. The target audience for the material is persons with diabetes rather than a general consumer audience. The NES reviewed the scientific evidence summaries and general dietary guidance portions of the fact sheet and provided feedback to the authors. The fact sheet has been posted and is available at: http://nccam.nih.gov/health/diabetes/supplements

4. **USDA Center for Nutrition Policy and Promotion (CNPP) and Food and Nutrition Service (FNS) *Loving Your Family, Feeding Their Future* Toolkit and Hand-outs**: The material was developed at the request of Supplemental Nutrition Assistance Program (SNAP—formerly called the "Food Stamp" program) nutritionists to reflect current SNAP language and guidance. The materials have a flexible format and can be used to deliver nutrition education and dietary guidance information to diverse groups with low literacy and numeracy skills. The content of the revised materials has been reduced to a single pager. All materials will be available in English and Spanish. The revised toolkit is available online: http://snap.nal.usda.gov/resource-library/nutrition-education-materials-fns/loving-your-family-feeding-their-future

5. **NIH Office of Dietary Supplements (ODS) *Magnesium QuickFacts Sheet*:** The NIH ODS *QuickFacts* are written for an educated, health-conscious lay audience and busy health providers. The fact sheets take a "just the facts" approach in providing information and advice and are limited in length to approximately five pages. Web links are provided to define scientific terms and guide the reader to other credible resources and references.

NES Reviews in Progress:

1. **USDA/CNPP *Healthy Eating on a Budget Web Content and Two-Week Menu with Supporting Resources***: The target audiences for the materials are low-income adults and families and educators working with families. The dietary guidance, menus and other

resources can be used by anyone wanting to create a nutritious diet while staying within their food budget.

Many recipes used in the sample menus provided were selected from the USDA Recipe Finder database on the SNAP-Ed Connection website (http://recipefinder.nal.usda.gov/). The menus are based on a 2,000 calorie USDA Food Pattern, which is an appropriate calorie level for some adult men, women, teens, and children 9 and older. The food group and nutrient content of the menus were analyzed using data from the SuperTracker online application. Food costs were calculated using the 2009 Foods Prices Database, adjusted to 2013 costs.

2. **USDA FNS WIC Program's updated *The Next Steps to Health for You and Your Family***: This submission updates the 1997 booklet entitled, *After You Deliver*. The target audience for the booklet is breastfeeding and non-breastfeeding post-partum mothers who are leaving the WIC Program. The content and design of the booklet is appropriate for diverse low-literacy and low SES target audiences. FNS contracted with APR, Inc. to conduct focus groups with English and Spanish-speaking program WIC participants to obtain feedback on the content and design of the booklet. The dietary guidance messages and content reflect the *Dietary Guidelines for Americans 2010* and incorporate the MyPlate logo and food group guidance.

NIH Health and Wellness Council

A subcommittee of the NIH Health and Wellness Council is working with ORS IT to develop a website pertaining to employee wellness. The site will include a comprehensive list of NIH resources and will provide easily accessible information on a variety of wellness topics, including nutrition. The site is expected to launch in February of 2014. If you are interested in participating the user acceptance testing phase, which will take place in January, please contact Rachel Fisher (rachel.fisher@nih.hhs.gov).

NEXT NCC MEETING

The next regularly scheduled NCC meeting will be on February 6, 2014.

ADJOURNMENT

The meeting was adjourned at 4:00 PM

LIST OF APPENDICES

Appendix A: NIH NCC Meeting Agenda for December 5, 2013
Appendix B: NIH NCC Meeting Attendees for December 5, 2013
Appendix C: Summary of Recommendations for Lifestyle Management

APPENDIX A: NIH NUTRITION COORDINATING COMMITTEE MEETING AGENDA

Thursday, December 5, 2013
2:00 – 4:00 pm
Building 45 (Natcher) Conference Room A

1. **Welcome**……..……..……..…….…….....Van Hubbard, DNRC

2. **Approval of Minutes of September 5, 2013 Meeting** ……..……..…Van Hubbard, DNRC

3. **Nutrition R&D Opportunities to Improve Global Health** …….Hillary Chen OSTP

4. **Guidance for Clinical Investigators, Sponsors and IRBs For IND** ……..……..Paula Trumbo, FDA

5. **ELSI Probiotics Framework** ….…..……..... Linda Duffy, NCCAM (PPWG)

6. **ODS Update** ……..…….…...Becky Costello, ODS

7. **ODPHP Update**…….Katrina Piercy, ODPHP

8. **Reports from NCC Members and Liaisons** ……..…..……..…. NCC Members

9. **Current DNRC Update of Activities**….....…….……..… DNRC Staff
    - Nutrition Education Subcommittee Update…..……Margaret McDowell*
    - International Committee Information….,……Pam Starke-Reed/Dan Raiten
    - HNRIM Update……...…..….Jim Krebs-Smith/Karen Regan
    - PPWG .....Crystal McDade-Ngutter
    - Wellness Workgroup .....Rachel Fisher/Margaret McDowell

10. **Next Meeting** – February 6, 2014

* Updates will be included in the minutes of the meeting only

APPENDIX B: NCC MEETING ATTENDEES FOR DECEMBER 5, 2013

Agencies, Institutes, Centers, and Divisions	Members Present	Members Absent	Alternates Present	Other Individuals Present
DNRC Director (Chair)	V Hubbard			
DNRC Deputy-Director	P Starke-Reed			
NIH MEMBERS				
NCI	S Ross			R Ballard-Barbash; R Flores; Y Kim
NHLBI	K McMurry			
NIDCR	M Cutting			
NIDDK		R Kuczmarski	M Evans	J Karimbakas; M Singh
NINDS				
NIAID		P Sato		
NIGMS		S Somers		
NICHD		G Grave	D Raiten	F Ashour; T Raju
NEI		S Gordon		
NIEHS		K Gray		
NIA	J Hannah			H Blanchard
NIAMS		X Wang		
NIDCD		B Wong		
NIMH		M Chavez		
NIMHD		D Tabor		
NIDA	S Volman			
NIAAA	R Breslow			
NINR	P Cotton			L Tully
NCCAM	L Duffy			C Pontzer
FIC		M Levintova		K Michaels
NHGRI		D Scholes		
NIH LIAISONS				
CC	A Courville			B Cines; C Shuman
CSR		R Garofalo		
NLM		M Corn		
OBSSR		D Sampson		
ODS		P Coates		B Costello; B Sorkin
OD/ODP		B Portnoy		
PRCC		D Stredrick		
AGENCY LIAISONS				
AHRQ		I Mabry-Hernandez		
CDC/NCCDPHP		J Seymour		
CDC/NCHS		N Ahluwalia		

Agencies, Institutes, Centers, and Divisions	Members Present	Members Absent	Alternates Present	Other Individuals Present
FDA		M Poos	S Blakely	S Dreher-Lesnick; R Kotz; J Leighton; J Patro; P Trumbo
HRSA		M Lawler		
IHS		T Brown		
ODPHP		H McPeak		S Goodwin; K Piercy
USDA/ARS		D Klurfeld		G Solano-Aguilar
USDA/NIFA		D Chester		I Walls
USDA/CNPP				
DOD				

DNRC: D Brown, R Fisher; S Fleischhacker; S Frazier; K Friedl; J Krebs-Smith; C McDade-Ngutter; M McDowell; K Regan

GUESTS: H Chen, White House, OSTP

Appendix C: Summary of Recommendations for Lifestyle Management

The Lifestyle CVD Final Recommendations Table

Recommendations	NHLBI Grade	NHLBI Evidence Statements	ACC/AHA COR	ACC/AHA LOE
DIET				
LDL-C - Advise adults who would benefit from LDL-C lowering* to:				
1. Consume a dietary pattern that emphasizes intake of vegetables, fruits, and whole grains; includes low-fat dairy products, poultry, fish, legumes, nontropical vegetable oils and nuts; and limits intake of sweets, sugar-sweetened beverages and red meats. a. Adapt this dietary pattern to appropriate calorie requirements, personal and cultural food preferences, and nutrition therapy for other medical conditions (including diabetes mellitus). b. Achieve this pattern by following plans such as the DASH dietary pattern, the USDA Food Pattern, or the AHA Diet.	A (Strong)	**CQ1:** ES4 (high), ES6 (low), ES8 (moderate), ES9 (moderate)	I	A
2. Aim for a dietary pattern that achieves 5% to 6% of calories from saturated fat.	A (Strong)	**CQ1:** ES11(high)	I	A
3. Reduce percent of calories from saturated fat.	A (Strong)	**CQ1:** ES11(high), ES12 (moderate), ES13 (moderate)	I	A
4. Reduce percent of calories from *trans* fat.	A (Strong)	**CQ1:** ES14 (moderate), ES15 (moderate)	I	A

BP - Advise adults who would benefit from BP lowering to:				
1. Consume a dietary pattern that emphasizes intake of vegetables, fruits, and whole grains; includes low-fat dairy products, poultry, fish, legumes, nontropical vegetable oils and nuts; and limits intake of sweets, sugar-sweetened beverages and red meats. a. Adapt this dietary pattern to appropriate calorie requirements, personal and cultural food preferences, and nutrition therapy for other medical conditions (including diabetes mellitus). b. Achieve this pattern by following plans such as the DASH dietary pattern, the USDA Food Pattern, or the AHA Diet.	A (Strong)	**CQ1:** ES1 (low) ES3 (high), ES5 (high), ES6 (low), ES7 (low), ES8 (moderate)	I	A
2. Lower sodium intake.	A (Strong)	**CQ2:** ES1 (high), ES2 (moderate), ES3 (high), ES4 (high), ES5 (high), ES8 (low), ES9 (low)	I	A
3. Advise adults to consume no more than 2,400 mg of sodium/day and that a further reduction of sodium intake to 1,500 mg/day can result in even greater reduction in BP. Even without achieving these goals, reducing sodium intake by at least 1,000 mg/ day lowers BP.	B (Moderate)	**CQ2:** ES2 (moderate), ES3 (high)	IIa	B
4. Combine the DASH dietary pattern with lower sodium intake.	A (Strong)	**CQ1:** ES3 (high), ES5 (high), ES8 (moderate) **CQ2:** ES1 (high), ES2 (moderate), ES3 (high), ES4 (high), ES5 (high), ES6 (moderate)	I	A
PHYSICAL ACTIVITY				
Lipids 1. In general, advise adults to engage in aerobic physical activity to reduce LDL-C and non-HDL-C: 3 to 4 sessions a week, lasting on average 40 minutes per session, and involving moderate-to-vigorous intensity physical activity.	B (Moderate)	**CQ3:** ES1 (moderate), ES2 (moderate), ES5 (low)	IIa	A
BP 1. In general, advise adults to engage in aerobic physical activity to lower BP: 3 to 4 sessions a week, lasting on average 40 minutes per session, and involving moderate-to-vigorous intensity physical activity.	B (Moderate)	**CQ3:** ES1 (high)	IIa	A

*Refer to 2013 Blood Cholesterol Guideline for guidance on who would benefit from LDL-C lowering (5).
ACC indicates American College of Cardiology; AHA, American Heart Association; BP, blood pressure; CQ, critical question; DASH, Dietary Approaches to Stop Hypertension; ES, evidence statement; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; NHLBI, National Heart, Lung, and Blood Institute; and USDA, U.S. Department of Agriculture.